



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,406	11/18/2005	Tomasz Troczynski	U008 0632/GSO	4838

720 7590 07/09/2009
OYEN, WIGGS, GREEN & MUTALA LLP
480 - THE STATION
601 WEST CORDOVA STREET
VANCOUVER, BC V6B 1G1
CANADA

EXAMINER

AL-AWADI, DANAH J

ART UNIT	PAPER NUMBER
----------	--------------

1615

MAIL DATE	DELIVERY MODE
-----------	---------------

07/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,406	Applicant(s) TROCZYNSKI ET AL.	
	Examiner DANAH AL-AWADI	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-9,11-13 and 37-43 is/are pending in the application.
- 4a) Of the above claim(s) 39-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-9,11-13,37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2 pages/12/18/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Applicant's amendments and remarks filed 12/18/2008. The Examiner acknowledges the following:

Claims 6, 10, 14-36, and 44-59 have been previously cancelled

Thus, claims 1-5,7-9, 11-13, 37, 38, and 39-43 represent all claims currently pending with claims 39-43 previously withdrawn.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statements (IDS) have been submitted for consideration

WITHDRAWN REJECTIONS

35 U.S.C. 102 (e)

Applicant's arguments, see page 3 line 7, filed 12/18/2008, with respect to the rejection(s) of claim(s) 1,2,8,9, and 13 under 35 U.S.C. 102 (e) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art references.

35 U.S.C. 103 (a)

Applicant's arguments, see page 5 lines 1-2, filed 12/18/2008, with respect to the rejection(s) of claim(s) 1,2,8,9, and 13 under 35 U.S.C. 102 (e) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art references.

NEW REJECTIONS

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7,8,13, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. US Patent 5,899,935 and Choi et al. 2000.

For pending claim 1 Ding et al. US Patent 5,899,935 (hereafter the '935 patent) teaches a stent with inorganic material such as brittle ceramic coatings applied by ion beam assisted deposition (abstract and the paragraph of line 55 column 3). With regards to pending claim 8, the '935 patent further discloses that the strands of the stent are made up of metal such as stainless steel (the paragraph of line 5 column 3).

Art Unit: 1615

The '935 patent does not teach a calcium phosphate coating on the substrate, however, Choi et al. "Ion-Beam-Assisted Deposition (IBAD) of Hydroxyapatite Coating Layer on Ti-Based Metal Substrate" (hereafter the "U" reference) teaches calcium phosphate layers of metal implants (abstract and the introduction of page 469). The calcium phosphate layer was formed on a titanium based metal substrate. The "U" reference further teaches a hydroxyapatite layer formed on the surface of a Ti-based alloy (paragraph 4 of the introduction page 469). The "U" reference also teaches forming a tricalcium phosphate coating (paragraph 1 of the results and discussion page 470).

With regards to the thickness of the calcium phosphate coating, the "U" reference teaches that the coating layers started out with a thickness of 700nm (0.7um) (paragraph 1 of the results and discussion page 470). It would have been prima facie obvious to optimize the coating thickness through routine experimentation.

With regards to the tensile bond strength, the "U" reference teaches that the ion-beam method does not require heat treatment to get a good bond strength and decreased dissolution rate (Fig. 6 and the last paragraph of page 471). Figure 4 teaches bond strengths of greater than about 40MPa.

With regards to the coating covering about 20% to about 90% of the surface of the substrate as stated in pending claim 7, the "U" reference teaches calcium phosphate coating of the substrate, therefore it is reasonable interpretation that coating covers about the entire substrate. Therefore, examiner considers the coating of the "U" reference to cover about 99% of the surface of the substrate.

Art Unit: 1615

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the '935 patent and the "U" reference to formulate a stent composed of ceramic material such as calcium phosphate and hydroxyapatite. One would have been motivated to do so because hydroxyapatite or other calcium phosphates, improve bioactivity of metal implants as well as lead to stabilization of implants with surrounding tissues. It would have been obvious to coat a stent with a ceramic such as calcium phosphate because the '935 patent teaches expandable stents have been coated with brittle ceramics. Furthermore, the "U" reference teaches that by employing the ion-beam assistance technique, a hydroxyapatite coating layer that has a high bond strength and at the same time a low dissolution rate can be deposited on a metal substrate (the last paragraph of page 471). This is advantageous because if the dissolution rate is faster than implants stabilization, the coating would be useless (second paragraph of the introduction on page 469). The "U" reference further teaches that if the bond strength of a coating layer with the metal substrate is weak, the layer may become separated from the implant during applications in the human body and the detached fragments would have adverse effects on the implant or tissue surrounding it (second paragraph of the introduction on page 469).

Claims 9 and 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. US Patent 5,899,935 and Choi et al. 2000 as applied to claims 1-5, 7,8,13, and 37 above, and further in view of Mancini et al. and Mitoh et al. US Patent 5,851,670.

The combination of the '935 patent, and the Choi et al. have been discussed supra and teaches that you can alter the ratio of Ca/P which would affect the rate dissolution (first

Art Unit: 1615

paragraph of page 472). The combination of the '935 patent and Choi et al. does not disclose that the calcium phosphate layer is porous and elutes a drug, however Mancini et al. "Porosity Determination in Thermally Sprayed Hydroxyapatite Coatings" (hereafter the "V" reference) teaches that as the crystallinity of the hydroxyapatite increases, the porosity also increases (abstract). The "V" reference does not teach that the pores elute a drug, however Mitoh et al. US Patent 5,851,670 (hereafter the '670 patent) teaches calcium phosphate particles that are porous and elute a drug (the paragraph of line 22 column 4, the paragraph of line 41 column 6). The '670 patent teaches that the pore size of the porous granules can be controlled by varying the size of the crystalline particles (the paragraph of line 47 column 4).

With regards to pending claim 11, the claim interpreted as broadly as possibly would encompass doubling the thickness of the calcium phosphate coating with drug. It would have been prima facie obvious to optimize the thickness of the coating.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the '935 patent, the "U" reference, "V" reference, and the '670 patent to formulate a stent with a calcium phosphate coating that is porous and elutes a drug. One would have been motivated to do so because having a biocompatible porous coating of calcium phosphate would provide for sustained release of drug delivery.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. US Patent 5,899,935, Choi et al. 2000, Mancini et al. and Mitoh et al. US Patent 5,851,670 as applied to claims 9 and 11 above, and further in view of Falotico et al. PG PUB 2001/0029351.

With regards to claim 11, the limitations have been discussed supra. The combination of the '935 patent, the "U" reference, "V" reference, and the '670 patent do not disclose two coating layers where a drug is present in each coating, however Falotico et al. PGPUB 2001/0029351 (hereafter the '351 publication) teaches an implant (stent) having two coatings where a drug is present in each coating (Figs 3-5). It would have been obvious to one of ordinary skill in the art to utilize two calcium phosphate coatings with a drug in each coating in order to create to provide the most efficacious treatment for post-angioplasty restenosis [0032].

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. US Patent 5,899,935, Choi et al. 2000, Mancini et al., Mitoh et al. US Patent 5,851,670 and Falotico et al. PGPUB 2001/0029351 as applied to claim 11 above, and further in view of Pacetti.

Pacetti discloses the stent is used to prevent restenosis and comprises a therapeutic drug (col 6. lines 45-52; col 10 lines 13-14). However, the modified Pacetti fails to expressly disclose the drug inhibits restenosis. Nevertheless, it is well known in the art for implants to have a coating comprising a drug for inhibiting restenosis, as taught by Falotico [0018],[0032]. It would have been obvious to one of ordinary skill in the art to include a drug for inhibiting restenosis in order to improve the treatment for restenosis [0032].

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. US Patent 5,899,935 and Choi et al. 2000, as applied to claims 1-5, 7,8,13, and 37 above, and further in view of Teller et al. 5,759,376.

The '935 patent and Choi et al have been discussed supra. The combination does not disclose a electrophoretically deposited coating, however Teller et al. 5,759,376 (hereafter the

Art Unit: 1615

'376 patent) discloses that it is well known in the art to apply calcium phosphate coatings via electrochemical deposition (abstract and the paragraph of line 5 column 1). It would have been obvious to one of ordinary skill in the art to apply the calcium phosphate layer via electrochemical deposition in order to produce uniform and thin calcium phosphate coatings, as desired.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danah Al-awadi whose telephone number is (571) 270-7668. The examiner can normally be reached on 9:00 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Danah Al-awadi/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615